

REMARKS/ARGUMENTS

Claims 1-5 and 7-16 are currently pending in the above-identified application.
Claim 6 has been cancelled in the present amendment.

Rejections Under 35 U.S.C. §112

In the Office Action of February 15, 2007, the Office maintained the rejection under 35 USC §112, second paragraph. The Office stated that because the ImCRAC of the instant claims may bind to an antibody induced by any number of species of Mycobacteria, it was unclear how one speciates a Mycobacterium by these methods if one only detects any antibody/antigen complex, i.e., either or both ImCRAC/host antibody or host antigen/added antibody.

In response, Applicants note that the Specification describes that each mycobacterial infection generates its own specific antibody response to a number of specified antigens. Analysis of the response results in distinguishing banding patterns of mycobacterial antigens for different Mycobacterial species. (Page 3, lines 9-17.) Each banding pattern is referred to as an "antigen bar code," and the patterns shown in the bar code are unique for a certain Mycobacterium species.

Thus, by analyzing the banding pattern of antigens recognized by antibodies, for example, the species can be determined, and immune responses, such as occur during therapy or vaccination, can be monitored. (Specification, page 4, lines 20-26.) Thus, the Examiner's concern about how one speciates by these methods is explained by the use of the antigen banding pattern that is detected, either by means of ImCRAC and host antibody response, and/or providing antibody to known antigens and detecting host sample antigen. The antibody that is provided, however, is capable of binding other mycobacterial antigens that may be present in the fluid sample, such as, e.g., ImCRACs other than the one that is the source of antigen in the first

step. As previously noted, both or just one type of these complexes may be present. The detecting of the two types of complexes can be carried out separately or together. (Page 9, lines 7-15.)

Combining the information gained from the ability to detect both antibody and antigen present in a sample provides a highly sensitive diagnostic test. For example, it has been found that several mycobacterial components are present in animal and human body fluids, the presence of which can be determined by using cross-reactions with a chosen set of antibodies in a reliable manner. (Specification, page 3, line 34 to page 4, line 4.)

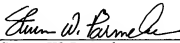
Accordingly, in view of the foregoing explanation, and the supporting description in the Specification, the claims are believed to be sufficiently definite as required under 35 USC §112, second paragraph. Reconsideration of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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